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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,201	01/27/2006	Artur Pfützner	MBP-033XX	8282
207 7590 04/10/2009 WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109				
EXAMINER				
KRUSE, DAVID H				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/566,201

Applicant(s)

PFITZNER ET AL.

Examiner

David H. Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-16 and 18-33 is/are pending in the application.
- 4a) Of the above claim(s) 16, 18, 19 and 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-14 and 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

STATUS OF THE APPLICATION

1. This Office action is in response to the Remarks filed 24 December 2008.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

3. Claims 15, 16, 18, 19 and 29-33 remain withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 16 March 2007.
4. This application contains claims 15, 16, 18, 19 and 29-33 drawn to an invention nonelected with traverse in the reply filed on 16 March 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144). See MPEP § 821.01.

Claim Rejections - 35 USC § 103

5. Claims 1, 2, 4-14 and 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cade et al (PGPPUB US-2004/0154051, published 5 August 2004, filed 12 March 2004) in view of Sato, S., (2000) DNA Res. 7 (2), 131-135 and in further view of Cade et al (U.S. Patent 6,706,952, filed 8 December 2000). This rejection is repeated for the reason of record as set forth in the last Office action mailed 25 September 2008. Applicant's arguments filed 24 December 2008 have been fully considered but they are not persuasive.

Applicants argue that none of the above prior art documents teaches or suggests a nucleic acid containing at least a first nucleotide sequence containing SEQ ID NO:2 that is operably linked to a second nucleotide sequence containing a transgene to be expressed, as recited in present claim 1. Applicants argue that none of the references teaches or suggests a promoter sequence including nucleotides 1-289 of SEQ ID NO:2, or a promoter comprising the entirety of SEQ ID NO:2 (paragraph spanning pages 8-9 of the Remarks).

Applicants argue that it should be noted that none of the cited prior art documents, taken either alone or in any combination, teaches or suggests the properties of the claimed subject matter of the present application. Applicants argue that the nucleic acid of the present invention allows the selective and inducible expression of a transgene in a suitable host, e.g. a transgenic plant, with unexpectedly high selectivity. Applicants argue that Example 3 showed a 5-fold induction of a transgene in a transgenic plant using a promoter according to the present claims. Applicants argue that no hint is given in any of the above prior art documents that the promoter contained in SEQ ID NO:2 is not only inducible by exogenous substances, but is also a very tight promoter, i.e. is characterized by a surprisingly low leakiness when no inducing agent is present. See, e.g., Example 5, which shows that a promoter according to the present claims was considerably less leaky than the PR-1a control. Applicants argue that this is a significant advantage since it allows for a very precise control of the expression of a transgene. Applicants argue that using the nucleic acid of the present invention, transgenic plants can be grown to a size sufficient to obtain enough plant material, and

expression of a transgene can then be selectively induced, resulting in the production of the desired product, e.g. a polypeptide, a protein or a RNA molecule (page 9, 2nd paragraph of the Remarks).

Applicants argue that the use of SEQ ID NO: 2 as a promoter for expression of a transgene is not even mentioned in any of the cited prior art documents, let alone the fact that this promoter is characterized by a surprisingly low leakiness (page 10, 1st paragraph of the Remarks).

Applicants argue that a person skilled in the art having knowledge of Cade 2004, Sato, and Cade 2000 would not have arrived at the claimed subject matter of the present application without inventive effort. Applicants argue that there was no suggestion in the cited references of using a promoter comprising SEQ ID NO: 2 to control the expression of a transgene; only portions of SEQ ID NO: 2 had been found to have promoter activity. Applicants argue that the combined references do not suggest in any way that by adding further 5' sequences to the promoter of Cade 2000 or Cade 2004 a salicylic acid-inducible promoter with superior selectivity and tight regulation of transgene expression would result. Applicants argue that there would have been no motivation to extend the Cade promoter sequences to encompass the present claims, or to select out from the genomic sequence of Sato the presently claimed SEQ ID NO:2 (page 10, 2nd paragraph of the Remarks).

Applicants' arguments have been fully considered but are not found to be persuasive. Applicants' evidence of unexpected results is merely argumentative. See, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well

settled that unexpected results must be established by factual evidence.” “[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument.”). The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Applicants provide no evidence that the salicylic acid inducible promoter taught by Cade *et al* (2004) would not have the same substantial characteristics of instant SEQ ID NO: 2. Cade *et al* (2004) teaches at Table 4 on page 22 that the NI16 promoter is inducible by salicylic acid and shows a 2.2-36.7 fold temporal increase in expression of a transgene in a transgenic plant in response to salicylic acid. Cade *et al* (2004) also teaches a recombinant vector comprising a coding sequence of interest operably lined to the NI16 promoter (claims 5 and 6), and a transgenic plant comprising a chimeric gene (claims 9 and 10). Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (MPEP 706.02).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.